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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,652	10/13/2000	Hai U. Wang	1802.1003-009	6630

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/04/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/687,652	Applicant(s) WANG ET AL.	
	Examiner Janet L Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-50 and 77-150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-50 and 77-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group VIII without traverse is acknowledged. The restriction requirement of paper no 5. is made final. Applicant has cancelled claims 1-44 and 51-75 and added 74 new claims. Claims 45-50 and 77-150 are therefore pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 45-50 and 77-150 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for inhibitors of interaction using eph and ephrin family members, does not reasonably provide enablement for methods using all artery- and vein-specific proteins, for methods of identifying activators, or for methods using "portions" of eph and ephrin family members. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

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Claims 45 and 77-87 are drawn to methods of screening for inhibitors of interactions between artery- and vein-specific proteins, and claims 48 and 114-124 are drawn to methods of screening for enhancers of such interactions. The specification describes an artery-specific molecule, ephrin B2, that interacts with a vein-specific molecule, eph B4. While one of skill could readily screen arterial and venous tissue for other ephrin and eph molecules, based on what is known about the structural features of these family members, the claims encompass molecules that need have no structural or functional relation whatsoever to the two molecules Applicant has described, including molecules that are not yet known in the art. The specification provides no basis for the skilled artisan to identify such molecules or even predict that they exist. No specific characteristics or structures of artery- or vein- specific proteins are set forth; since ephrins and their receptors are widely distributed (Pasquale, Current Opinion in Cell Biology, 1997, vol. 9, pp. 608-615), the prior art encompassing their structural and functional requirements provides no guidance for identifying any other species of artery- or vein- specific molecule. Thus, without further guidance as to the characteristics of artery- and vein-specific molecules, and teachings to indicate that such molecules exist, one of skill in the art would not predictably be able to identify and use such molecules. Thus it would require undue experimentation for one of skill the art to practice Applicant's methods as broadly claimed.

Claims 48-50 and 114-150 are drawn to methods of identifying molecules that enhance interaction between artery- and vein-specific molecules. However, no guidance is presented that such molecules exist and thus could predictably be identified. While blocking the interaction between two molecules, for example by an antibody or a competing peptide, is art standard, enhancement of an interaction is less predictable. Applicant has not taught how the interaction

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of a receptor and ligand, or other artery- and vein-specific molecules, might be enhanced. More direction than is present in the instant specification is required so that one of skill in the art would know what the characteristics of such factors might be, and how they might be identified, so that one of skill could use Applicant's invention with an expectation of success. In the absence of such guidance, given the unpredictability of identifying enhancing factors, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

Claims 46, 47, 49, 50, 88-113, and 125-137 are drawn to methods using "portions" of ephrin and eph molecules to screen for enhancers or inhibitors of interaction. However, Applicant has not described the "portions" of such molecules that are required or could be used in Applicant's methods. No necessary structural characteristics by which the appropriate "portions" of ephs and ephrins could be identified are set forth. Thus, one of skill in the art could not readily determine what portions of these molecules could be used in screens to identify enhancers or inhibitors, and it would require undue experimentation for the skilled artisan to make and use such portions.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 46, 47, 49, 50, 88-113, and 125-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite in the recitation of a "portion". Applicant has not defined a "portion" in the specification; one of skill in the art would not know the size or other characteristics of the molecules Applicants considered to be "portions".

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

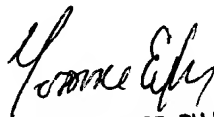
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 31, 2002


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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